PRESENTATION

Comparative analysis of regulatory policy on drug pricing in USA, Japan, and European Union

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Comparative Analysis of regulatory policy on drug pricing in USA, Japan, and European Union

Content

Regulatory Policy

- **European Union**

1. EU drug regulatory system
2. The EU regulatory system for medicines

- **(FDA or USFDA)**

1) WHAT USFDA REGULATES
2) RESPONSIBILITY OF FDA
3) MISSION OF FDA

Regulatory Policy

- Regulatory policy is about achieving government's objectives through the use of regulations, laws, and other instruments to deliver better economic and social outcomes and thus enhance the life of citizens and business.

Drug regulation is the control of drug use by international agreement and/or by regulatory authorities such as -

- **The US Food and Drug Administration (FDA),**
- **The European Medicinal Agency (EMA)**
- **Japanese Pharmaceutical and Medical Devices Agency (PMDA).**

This includes regulations concerned with the development, approval, manufacturing and marketing of drugs.

European Union

European Union Regulatory Requirements –

- The Political Union also known as the European Union was established in 1993 with the aim of achieving political and economic integration.
- The EU includes 28 member states of Europe.
- • The total population of the EU is estimated at 500 million

- **In the EU there are two regulatory measures when a drug is approved in the market**
- 1. Application for clinical examination (accredited member state)
- 2. Market authorization (authorized by both member states and intermediate level)

EU drug regulatory system

- The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 31 EEA countries.

The network is supported by a pool of thousands of experts drawn from across Europe, allowing it to source the best possible scientific expertise for the regulation of medicines in the EU and to provide scientific advice of the highest quality.

The EU regulatory system for medicines

Marketing authorizations

Pricing and reimbursement

The role of the European Commission

The role of EMA

Authorisation and supervision of manufacturers

Safety monitoring of medicines

Clinical trials

International cooperation

(FDA or USFDA)

The U.S. Food and Drug Administration (FDA or USFDA) is an business enterprise of the united states Department of Health and Human Services and is chargeable for regulating and overseeing the safety of foods, dietary supplements, drugs, vaccines, biological medicinal products.

products, blood products, medical devices, reradiation-emittingevices, veterinary products and cosmetics

WHAT USFDA REGULATES

- Biologics
- Food additives
- Dietary supplements
- Product standards and develop improved testing's methods
- Cosmetics
- Labeling
- OTC and prescription drug labeling
- Drug manufacturing standards
- Foods
- Safety of all food products (except meat and poultry)
- Medical devices from simple items like tongue depressors, to complex technologies such as heart pacemakers

RESPONSIBILITY OF FDA

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective.
- Protecting the public from electronic product radiation.
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products.
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health.

MISSION OF FDA

- To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.
- With respect to such products, protect the public health by ensuring that the food are safe, Wholesome, sanitary, and properly labelled; human and veterinary drugs are safe and effective

there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labelled, and public health and safety are protected from the electronic product radiation.

- Participates through appropriate process with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate arrangements

Regulatory Req. in Japan

MHLW:

- The Ministry of Health, Labour, and Welfare (MHLW) was established by a merger of the Ministry of Health and Welfare (MHW) and so the Ministry of Labour, on January 6, 2001.
- The MHLW, that was originally established in 1938, has been guilty of the event and promotion of financial aid, welfare and public health, and also the new organization features a similar task.
- It consists of the ministry proper, related institutions, councils, native branches, and an external organization.

FUNCTION OF MHLW

- Public Hygiene:
- Human Resources Development

PMDA (pharmaceuticals and medical devices agency)

PMDA is a Japanese regulatory organization that works with the ministry of fitness and hard work welfare (MHLW).

The PMDA become hooked up in April 2004 to offer offerings withinside the area of drug and scientific tool opinions, post-advertising and marketing protection measures, and remedy offerings for damaging fitness effects.

Our responsibility is to guard public fitness via way of means of making sure the protection and pleasant of drugs and scientific devices.

The PMDA's function is to offer consultations on medical trials of latest pills and scientific devices, and to behavior validation opinions and surveys at the reliability of exercise data.

Function of PMDA

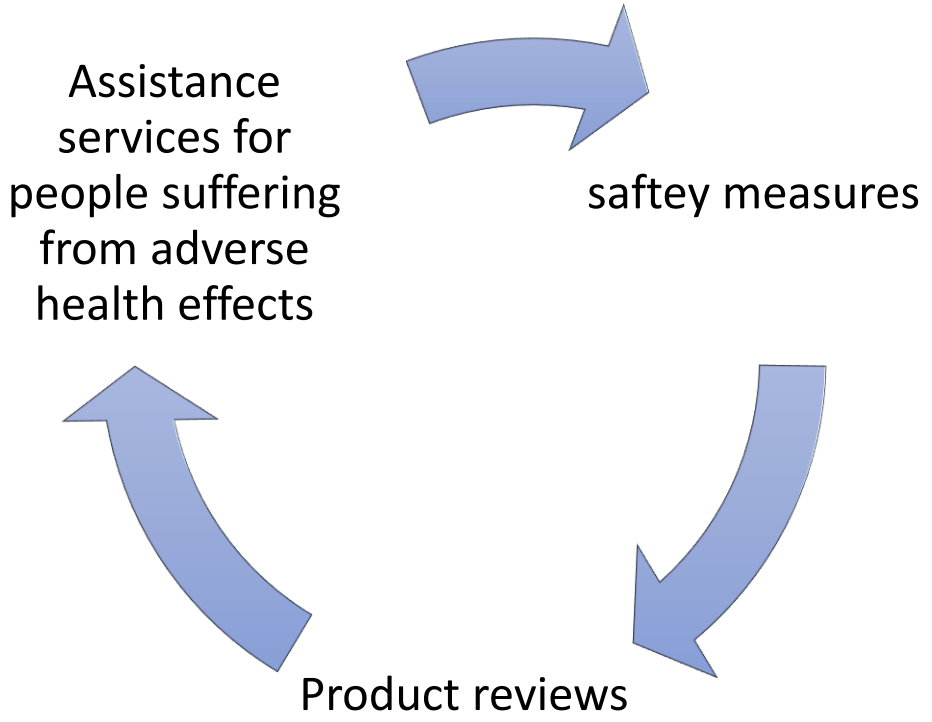
- Drug and Medical Device Testing Scientific review of market approval practices based on the Japanese Drug Law. Advice on the preparation of dossiers for clinical studies or approval procedures (New Drug Application (NDA)

- PMDA -JAPAN is run by CEO Tatsuya Konodo.

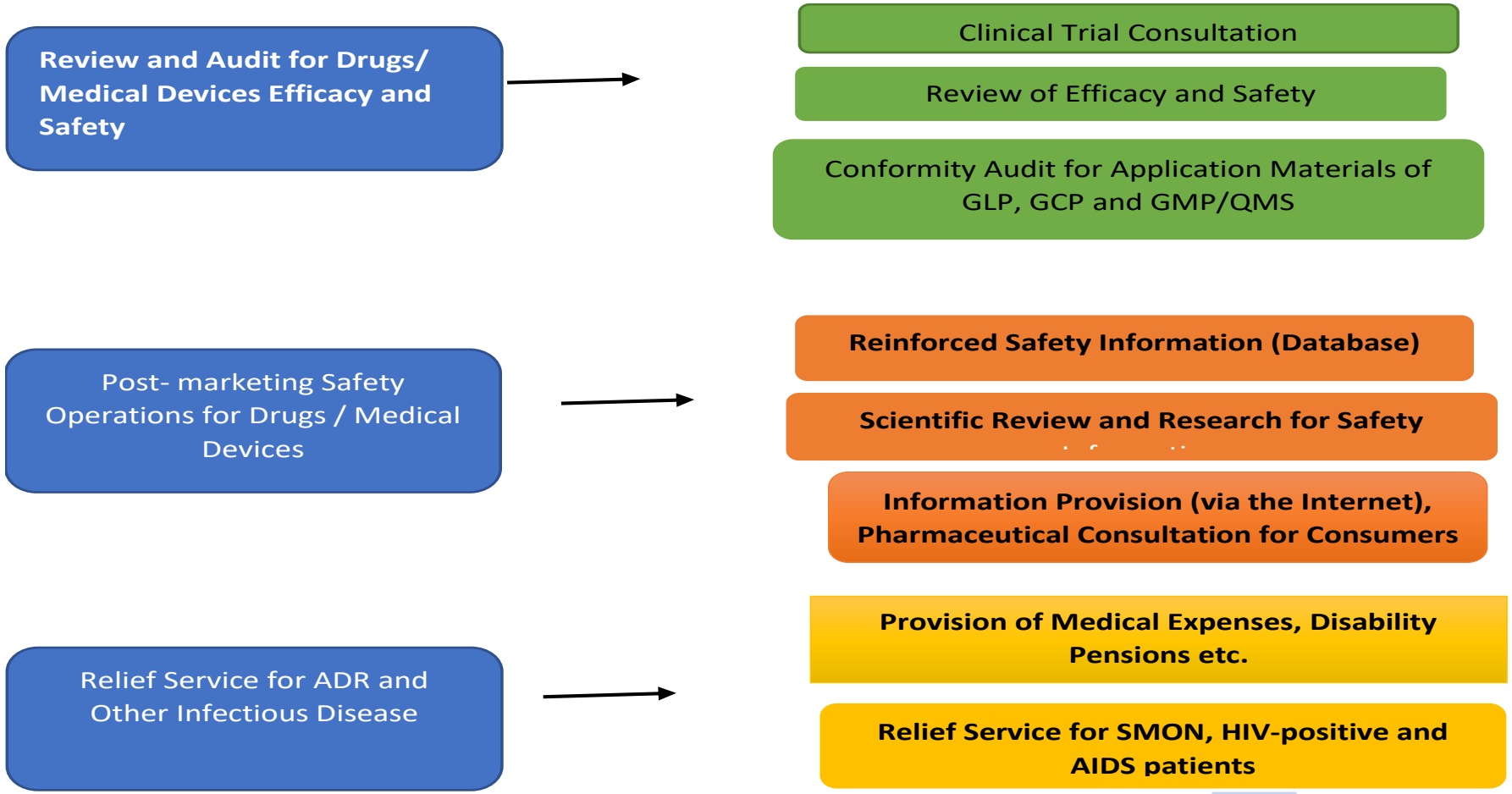
- Capital -- Tokyo
- Language -- Japanese
- Ethnic groups -- 98.5% Japanese
  0.5% Korea
  0.4 % Brazilian

- GDP -- $ 4.843 trillion
- Currency -- yen
- Market status -- second largest pharmaceutical market in the world.

PMDA works on 3 core services, a safe education system



PMDA three major functions/tasks



Effective regulation of drug requires a variety of functions:

- Guaranteeing the safety, efficacy and quality of drugs.
- Licensing of premises, persons and practices.
- Inspection of manufacturing facilities and distribution channels.
- Product assessment and registration.
- Adverse drug reaction monitoring.
- Quality control.
- Control of drug promotion and advertising.

The drug regulation consists of:

1. Drug Laws

2. Drug Regulatory Agencies

3. Drug Regulatory Boards

4. Quality Control

5. Drug Information Centres.

Thank you